

PRV

PATENT- OCH REGISTRERINGSVERKET
Patentavdelningen

SE00/1278

REC'D 04 SEP 2000

WMO

PCT

4

Intyg
Certificate

Härmed intygas att bifogade kopior överensstämmer med de handlingar som ursprungligen ingivits till Patent- och registreringsverket i nedannämnda ansökan.

This is to certify that the annexed is a true copy of the documents as originally filed with the Patent- and Registration Office in connection with the following patent application.

(71) Sökande SHL Medical AB, Nacka SE
Applicant (s)

(21) Patentansökningsnummer 9903663-4
Patent application number

(86) Ingivningsdatum 1999-10-12
Date of filing

Stockholm, 2000-08-14

För Patent- och registreringsverket
For the Patent- and Registration Office

A. Södervall
Anita Södervall

Avgift
Fee

PRIORITY
DOCUMENT
SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR (b)

BEST AVAILABLE COPY

PATENT- OCH
REGISTRERINGSVERKET
SWEDEN

Postadress/Adress
Box 5055
S-102 42 STOCKHOLM

Telefon/Phone
+46 8 782 25 00
Vx 08-782 25 00

Telex
17978
PATOREG S

Telefax
+46 8 666 02 86
08-666 02 86

INHALER SAFETY DEVICE

TECHNICAL FIELD

The present invention relates to a device for an inhaler, which inhaler 5 comprises an air passage inside the inhaler, an opening intended for inhalation of medicament in fluid connection with said air passage, means for delivering a dose of medicament into said air passage, means for activating said dose delivering means, wherein said activating means is activated by an air flow through said air passage.

10

BACKGROUND OF THE INVENTION

Inhalers for inhaling medicament into the respiratory tract comprise some sort of opening, typically also with a mouthpiece, and an air flow passage inside the inhaler in communication with the opening. A 15 compartment containing medicament and dose delivering means are also arranged and in communication with the air passage so that, when the patient inhales, air and medicament will mix in the air passage and will be inhaled by the patient.

20 A plurality of inhalers present on the market are provided with breath activated dose delivering means, so called breath activated inhalers. These function so as to deliver a dose of medicament when the patient inhales, i e when there is an air flow present in the air passage. In contrast to inhalers where the patient physically has to 25 activate the dose delivering means, e g by pressing parts of the inhaler, manoeuvring levers and the like, the breath activated inhalers are triggered by the inhalation. This provides a more reliable dose delivery to the patient because the patient no longer has to time the inhalation with physical activation of the inhaler.

30

A drawback with these breath activated inhalers is unintentional or accidental activation of the inhaler, especially by children. A child

often registers the activities of the adults and tries to do the same thing as them. If for example a parent uses an inhaler to inhale medicament, it is very likely that the child finds that interesting and would like to do the same. If the inhaler is then left within the child's reach it is likely that it would try to inhale. The inhaler would then be triggered to deliver a dose of medicament which the child unintentionally could inhale. Since these medicaments sometimes are quite potent, or even lethal, there is a risk that the child will suffer from poisoning which could lead to serious consequences.

10

BRIEF DESCRIPTION OF THE INVENTION

The aim of the present invention is to avoid the above mentioned problems concerning unintentional/accidental activation of breath activated inhalers.

15

This aim is obtained by a device for a breath activated inhaler where the device comprises user operated safety means arranged and positioned such that it prevents activation of said activating means when the safety means is in a non-operated state.

20

According to one aspect of the invention it is characterised in that said safety device comprises an auxiliary air passage in communication with the inhalation air passage and in communication with the outside of the inhaler via at least one opening, and user operated means for blocking said auxiliary air passage when an inhalation of medicament is to be performed.

30

According to yet an aspect of the invention it is characterised in that the user operated means comprises parts of a hand of a user of the inhaler.

According to a further aspect of the invention, it is characterised in that there are at least two openings and that they are arranged such on the inhaler that they cannot be reached by the fingers of a child's one hand. Further the openings may be arranged such on the inhaler

5 that they cannot be reached by the fingers of an adults one hand and/or that the size of the opening is such that a finger of a child cannot block the opening.

10 The advantage of the invention over prior art is that when the safety means is not operated, any unintentional inhalation through the inhaler will not affect the activating means. Since the activating means is triggered by the air flow through the inhaler during inhalation, a manipulation of this air flow preventing the activating means to be unintentionally activated provides an easy and reliable

15 safety device.

20 The blocking of the auxiliary air passage may be obtained in many different ways, for example by the finger or hand of the user, by flaps or lids or the like.

25 Preferably, the openings are arranged such on the inhaler, and/or have such sizes, that only an adult is able of blocking the openings in order to activate the activating means upon inhalation.

30 It is to be noted that the present invention may be used with all breath activated or breath controlled inhalers, regardless of type of medicament.

These and other aspects of, and advantages with, the present invention will become apparent from the following detailed description of illustrative embodiments and from the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the detailed description of the invention, reference will be made to the accompanying drawings, of which:

5 Fig. 1 shows a side view in cross-section of an inhaler for aerosol-driven medicament with a device according to the invention, and

10 Fig. 2 shows a part view in cross-section of an inhaler for powder medicament with a device according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 shows, as an example, an inhaler for aerosol-driven medicament which may utilise the present invention. The inhaler

15 comprises a housing 10 with an opening 12 intended for inhalation of a dose of medicament. Inside the housing is arranged a canister 14 containing the medicament and aerosol as propellant. The canister is provided with dose delivery mechanism comprising a spring-loaded stem 16. The stem is provided with a passage extending into the

20 canister. The stem/lower part of the canister is supported by a holding/fixating device 18.

At the opposite end of the canister stem, an activating means 20 is arranged. It comprises in the embodiment shown a spring 22 with one end pressing on the canister and the other end supported by a holder 24.

25 The activating means further comprises an air inlet 26 arranged in the inhaler housing and a flap 28 pivotally arranged adjacent the air intake. When the flap is in a resting, inactivated, position, it covers the air intake. Arranged in contact with the flap is a holding means 30, which in the embodiment shown comprises an elongated arm

extending alongside the canister side. The arm is at its lower end arranged with a ledge 32. When in a resting position, the arm and the ledge holds the canister in an inactivated position against the force of the spring. The interior of the inhaler, from the inhalation opening to the air intake forms an air passage.

The inhaler further comprises a safety means. It comprises at least one auxiliary air intake 34 arranged to communicate with the inhaler air passage, forming an auxiliary air passage with the inhalation 10 opening, where the intake is positioned between the inhalation opening and the flap/main air intake. Further auxiliary air intakes 36 are shown with broken lines.

In normal use of the inhaler, without the safety means, the start of 15 an inhalation through the inhalation opening causes a pressure difference between the interior and the exterior of the inhaler. This pressure difference causes the flap to pivot, thereby causing an air flow through the inhaler from the air intake to the inhalation opening. The pivoting movement of the flap acts on the elongated arm 20 so that the arm is swung away somewhat from the canister. This causes the ledge to release the canister from its inactivated position. The force of the spring causes the canister to depress whereby the stem is pressed into the canister and a dose is delivered to the inhalation opening, which dose is inhaled by the patient.

25 When the safety device according to the invention is used with the inhaler and the auxiliary air intake is closed, the function is as described above.

30 If on the other hand someone tries to inhale without closing the auxiliary air intake, an air flow passage is created from the auxiliary air intake to the inhalation opening, thereby preventing a build-up of

a pressure difference inside the inhaler. Because no pressure difference is created, the flap will not be affected by the inhalation.

5 Fig. 2 shows another example of an inhaler where the present invention is utilised. The inhaler shown is intended for medicament in powder form. The inhaler comprises a housing 40. At one end of the housing a mouthpiece 42 with an inhalation opening 44 is arranged. The mouthpiece can be protected by a protective cover 46.

10 10 Arranged inside the opening is a means for enabling access to medicament. The means comprises an elongated body 48 with a passage through its length, hereafter named outlet passage. One end 50, the one facing inwards, is arranged with sharpened edges. The elongated body is slidably supported in a hole in the opening, 15 whereby the other end of the elongated body is arranged in the opening. An activating means is arranged to the elongated body, comprising an air intake 52, a flap 54 pivotally arranged adjacent the air intake and a mechanism 56 designed to be able of moving the elongated body inwards when the flap is opened.

20 20 Further inside the inhaler and the elongated body a wheel 58 is rotatably arranged. The wheel is arranged with a plurality of recesses 60 and means for rotating the wheel to different positions.

25 25 The medicament is packaged in blisters, where each blister enclosure contains one dose of medicament. The blister enclosures are placed in the recesses.

30 30 The inhaler further comprises a safety means. It comprises at least one auxiliary air intake 80 arranged to communicate with the inhaler interior, forming an auxiliary air passage with the inhalation opening.

During normal use, without the device according to the invention, the inhalation causes a pressure difference between the interior and the exterior of the inhaler. This pressure difference causes the flap 54 to open and an air flow to be created through the air intake 52 and the 5 passage of the elongated body 48. The movement of the flap causes the activating means to move the elongated body forward so that its pointed end penetrates the blister enclosure whereby a passage between the interior of the enclosure and the inhalation opening is created so that medicament is inhaled.

10

When the safety device according to the invention is used with the inhaler and the auxiliary air intake 80 is closed, the function is as described above.

15 If on the other hand someone tries to inhale without closing the auxiliary air intake, an air flow passage is created from the auxiliary air intake 80 through passage of the elongated body to the inhalation opening, thereby preventing a build-up of a pressure difference inside the inhaler. Because no pressure difference is created, the flap will 20 not be affected by the inhalation.

In this context it is to be understood that the auxiliary air intake may be closed or blocked by the fingers of the patient or by a mechanical means. Since the greatest risk of unintentional inhalation is from 25 children, the air intakes should preferably be placed so that a child cannot close the auxiliary intake without great effort.

There are several ways of obtaining this. One way is that the size of the auxiliary air intake is such that a child's finger cannot block it. 30 Another way is that there are several auxiliary air intakes arranged in the inhaler housing so that it is difficult for a child to place several fingers over all of the intakes. Further the distance between the

intakes could be such that it is impossible for a child's hand to reach all the intakes.

5 If the medicament is of a very potent, toxic, or even lethal kind, if inhaled wrongly, the device could be designed such, and with the auxiliary air intakes positioned such that both hands are needed in order to cover or block all intakes.

10 In this context it is to be noted that, if more than one auxiliary air intake is used, the activating means is arranged such that it is only activated when a pressure drop corresponding to a complete blocking of all intakes is reached, i e it shall not be sufficient to block some of the auxiliary air intakes in order to activate the inhaler. By providing different number of openings and by arranging these with different 15 configurations, different "levels of security" may be obtained with the present invention.

PATENT CLAIMS

1. Device for an inhaler, which inhaler comprises an air passage inside the inhaler, an opening (12, 44) intended for inhalation of medicament in fluid connection with said air passage, means for delivering a dose of medicament (14, 16, 22, 48, 50, 60) into said air passage, means for activating said dose delivering means (26, 28 30, 52, 54, 56), wherein said activating means is activated by an air flow through said air passage, **c h a r a c t e r i s e d** in that the device comprises user operated safety means (34, 80) arranged and positioned such that it prevents activation of said activating means when the safety means is in a non-operated state.
2. Device according to claim 1, **c h a r a c t e r i s e d** in that said safety device comprises an auxiliary air passage in communication with the inhalation air passage and in communication with the outside of the inhaler via at least one opening, and user operated means for blocking said auxiliary air passage when an inhalation of medicament is to be performed.
3. Device according to claim 2, **c h a r a c t e r i s e d** in that the user operated means comprises parts of a hand of a user of the inhaler.
4. Device according to claim 3, **c h a r a c t e r i s e d** in that there are at least two openings and that they are arranged such on the inhaler that they cannot be reached by the fingers of a child's one hand.
5. Device according to claim 3, **c h a r a c t e r i s e d** in that there are at least two openings and that they are arranged such on the inhaler that they cannot be reached by the fingers of an adults one hand.

6. Device according to claim 3, characterised in that the size of the opening is such that a finger of a child cannot block the opening.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65
66
67
68
69
70
71
72
73
74
75
76
77
78
79
80
81
82
83
84
85
86
87
88
89
90
91
92
93
94
95
96
97
98
99
100
101
102
103
104
105
106
107
108
109
110
111
112
113
114
115
116
117
118
119
120
121
122
123
124
125
126
127
128
129
130
131
132
133
134
135
136
137
138
139
140
141
142
143
144
145
146
147
148
149
150
151
152
153
154
155
156
157
158
159
160
161
162
163
164
165
166
167
168
169
170
171
172
173
174
175
176
177
178
179
180
181
182
183
184
185
186
187
188
189
190
191
192
193
194
195
196
197
198
199
200
201
202
203
204
205
206
207
208
209
210
211
212
213
214
215
216
217
218
219
220
221
222
223
224
225
226
227
228
229
230
231
232
233
234
235
236
237
238
239
240
241
242
243
244
245
246
247
248
249
250
251
252
253
254
255
256
257
258
259
259
260
261
262
263
264
265
266
267
268
269
270
271
272
273
274
275
276
277
278
279
279
280
281
282
283
284
285
286
287
288
289
289
290
291
292
293
294
295
296
297
298
299
299
300
301
302
303
304
305
306
307
308
309
309
310
311
312
313
314
315
316
317
318
319
319
320
321
322
323
324
325
326
327
328
329
329
330
331
332
333
334
335
336
337
338
339
339
340
341
342
343
344
345
346
347
348
349
349
350
351
352
353
354
355
356
357
358
359
359
360
361
362
363
364
365
366
367
368
369
369
370
371
372
373
374
375
376
377
378
379
379
380
381
382
383
384
385
386
387
388
389
389
390
391
392
393
394
395
396
397
398
399
399
400
401
402
403
404
405
406
407
408
409
409
410
411
412
413
414
415
416
417
418
419
419
420
421
422
423
424
425
426
427
428
429
429
430
431
432
433
434
435
436
437
438
439
439
440
441
442
443
444
445
446
447
448
449
449
450
451
452
453
454
455
456
457
458
459
459
460
461
462
463
464
465
466
467
468
469
469
470
471
472
473
474
475
476
477
478
479
479
480
481
482
483
484
485
486
487
488
489
489
490
491
492
493
494
495
496
497
498
499
499
500
501
502
503
504
505
506
507
508
509
509
510
511
512
513
514
515
516
517
518
519
519
520
521
522
523
524
525
526
527
528
529
529
530
531
532
533
534
535
536
537
538
539
539
540
541
542
543
544
545
546
547
548
549
549
550
551
552
553
554
555
556
557
558
559
559
560
561
562
563
564
565
566
567
568
569
569
570
571
572
573
574
575
576
577
578
579
579
580
581
582
583
584
585
586
587
588
589
589
590
591
592
593
594
595
596
597
598
599
599
600
601
602
603
604
605
606
607
608
609
609
610
611
612
613
614
615
616
617
618
619
619
620
621
622
623
624
625
626
627
628
629
629
630
631
632
633
634
635
636
637
638
639
639
640
641
642
643
644
645
646
647
648
649
649
650
651
652
653
654
655
656
657
658
659
659
660
661
662
663
664
665
666
667
668
669
669
670
671
672
673
674
675
676
677
678
679
679
680
681
682
683
684
685
686
687
688
689
689
690
691
692
693
694
695
696
697
698
699
699
700
701
702
703
704
705
706
707
708
709
709
710
711
712
713
714
715
716
717
718
719
719
720
721
722
723
724
725
726
727
728
729
729
730
731
732
733
734
735
736
737
738
739
739
740
741
742
743
744
745
746
747
748
749
749
750
751
752
753
754
755
756
757
758
759
759
760
761
762
763
764
765
766
767
768
769
769
770
771
772
773
774
775
776
777
778
779
779
780
781
782
783
784
785
786
787
788
789
789
790
791
792
793
794
795
796
797
798
799
799
800
801
802
803
804
805
806
807
808
809
809
810
811
812
813
814
815
816
817
818
819
819
820
821
822
823
824
825
826
827
828
829
829
830
831
832
833
834
835
836
837
838
839
839
840
841
842
843
844
845
846
847
848
849
849
850
851
852
853
854
855
856
857
858
859
859
860
861
862
863
864
865
866
867
868
869
869
870
871
872
873
874
875
876
877
878
879
879
880
881
882
883
884
885
886
887
888
889
889
890
891
892
893
894
895
896
897
898
899
899
900
901
902
903
904
905
906
907
908
909
909
910
911
912
913
914
915
916
917
918
919
919
920
921
922
923
924
925
926
927
928
929
929
930
931
932
933
934
935
936
937
938
939
939
940
941
942
943
944
945
946
947
948
949
949
950
951
952
953
954
955
956
957
958
959
959
960
961
962
963
964
965
966
967
968
969
969
970
971
972
973
974
975
976
977
978
979
979
980
981
982
983
984
985
986
987
988
989
989
990
991
992
993
994
995
996
997
998
999
999
1000

ABSTRACT

The present invention relates to a device for an inhaler, which inhaler comprises an air passage inside the inhaler, an opening (12, 44) intended for inhalation of medicament in fluid connection with said air passage, means for delivering a dose of medicament (14, 16, 22, 48, 50, 60) into said air passage, means for activating said dose delivering means (26, 28 30, 52, 54, 56), wherein said activating means is activated by an air flow through said air passage. The device is characterised in that the device comprises user operated safety means (34, 80) arranged and positioned such that it prevents activation of said activating means when the safety means is in a non-operated state.

(Fig. 1)

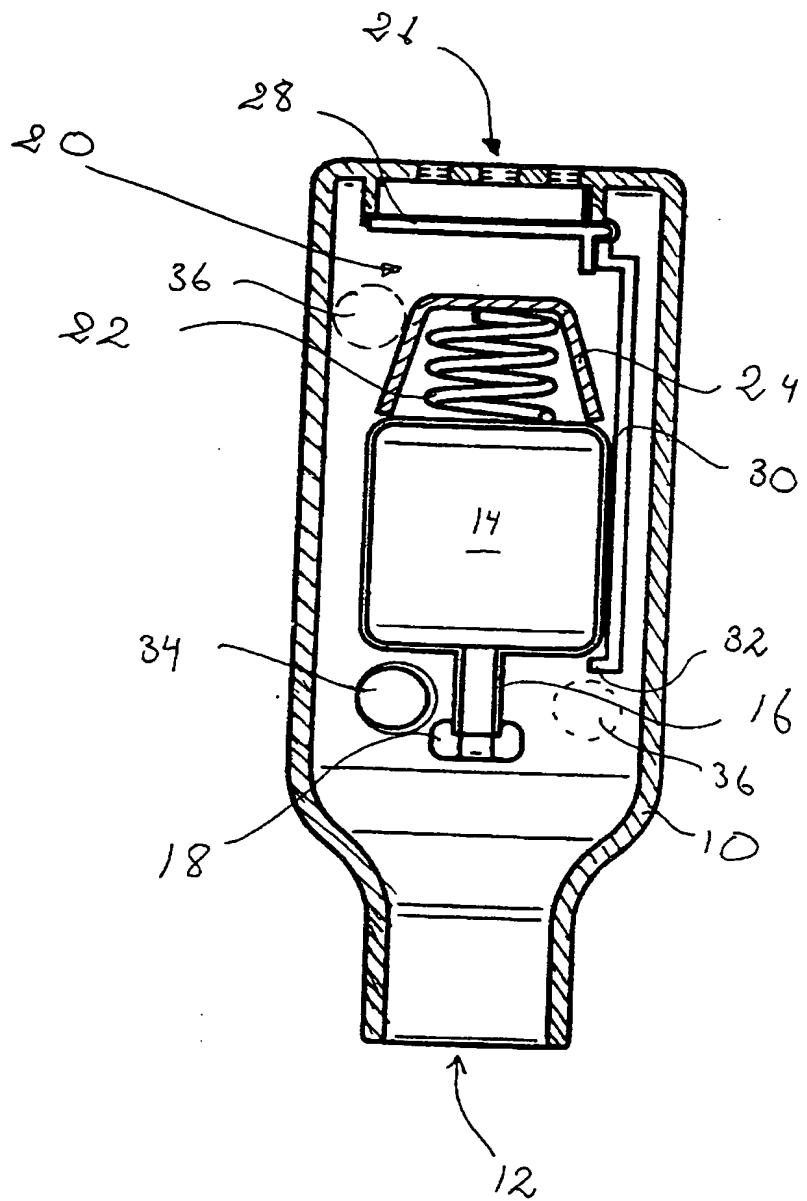


Fig. 1

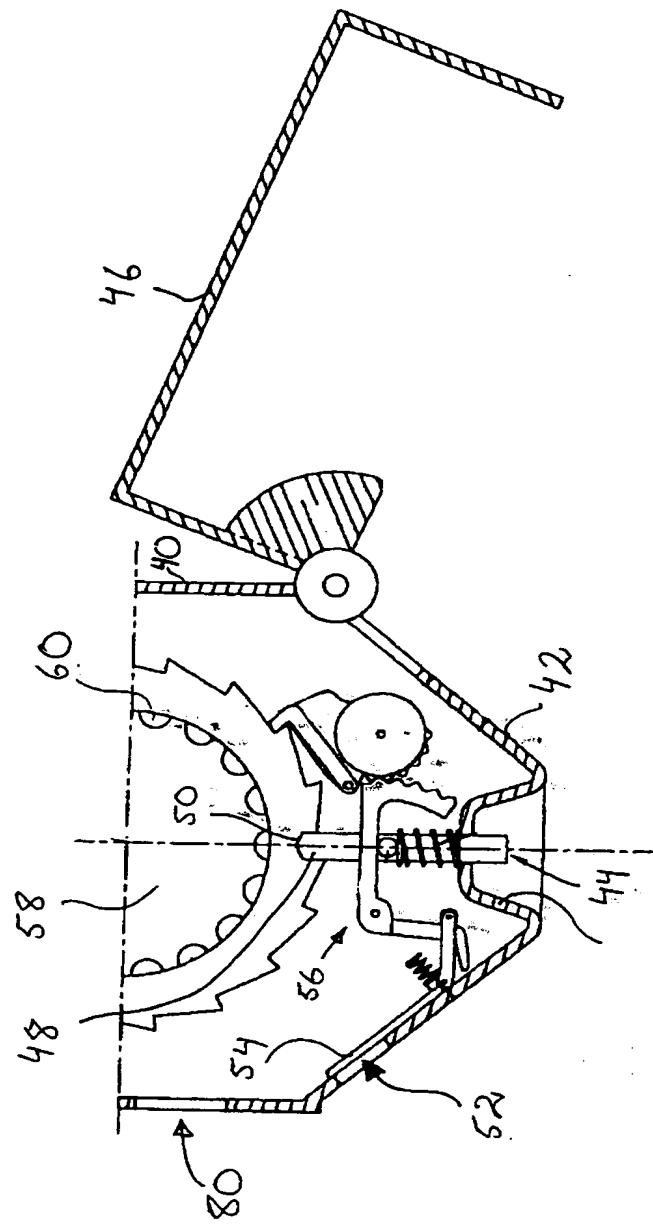


Fig. 2